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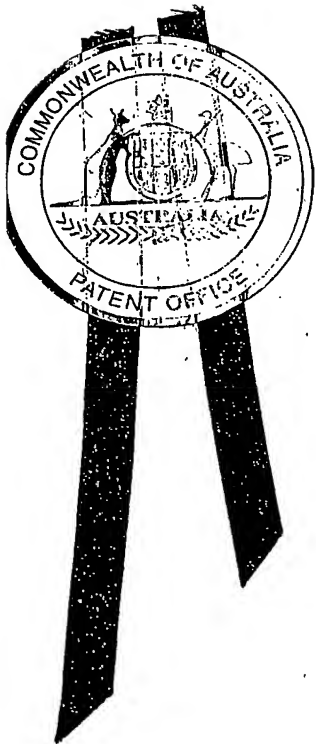
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SUPPORT AND SALES hereby certify that annexed is a true copy of the
Provisional specification in connection with Application No. PS 0976 for a
patent by COCHLEAR LIMITED as filed on 08 March 2002.



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AUSTRALIA

Patents Act 1990

Cochlear Limited

PROVISIONAL SPECIFICATION

Invention Title:

A cochlear implant

The invention is described in the following statement:

Field of the Invention

The present invention relates to a cochlear implant system. In particular, the present invention relates to a cochlear implant system that can be used
5 with or without a magnetic alignment system for the transmitter and receiver coils of the system.

Background of the Invention

10 In many people who are profoundly deaf, the reason for deafness is absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into nerve impulses. These people are unable to derive suitable benefit from conventional hearing aid systems, no matter how loud the acoustic stimulus is made, because there is damage to or absence of the
15 mechanism for nerve impulses to be generated from sound in the normal manner.

It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical
20 stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve. US Patent 4532930, the contents of which are incorporated herein by reference, provides a description of one type of traditional cochlear implant system.

25 Typically, cochlear implant systems have consisted of essentially two components, an external component commonly referred to as a processor unit and an internal implanted component commonly referred to as a receiver/stimulator unit. Traditionally, both of these components have
30 cooperated together to provide the sound sensation to a user.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that converts the detected sounds, particularly speech, into a coded
35 signal, a power source such as a battery, and an external transmitter coil.

The coded signal output by the speech processor is transmitted transcutaneously to the implanted stimulator/receiver unit situated within a recess of the temporal bone of the user. This transcutaneous transmission occurs via the external transmitter coil which is positioned to communicate with
5 an implanted receiver coil provided with the stimulator/receiver unit.

This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted stimulator/receiver unit. Conventionally, this link has
10 been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

The implanted stimulator/receiver unit traditionally includes a receiver coil that receives the coded signal and power from the external processor
15 component, and a stimulator that processes the coded signal and outputs a stimulation signal to an intracochlear electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

20 Traditionally, the external componentry has been carried on the body of the user, such as in a pocket of the user's clothing, a belt pouch or in a harness, while the microphone has been mounted on a clip behind the ear or on the lapel of the user.

25 More recently, due in the main to improvements in technology, the physical dimensions of the speech processor have been able to be reduced allowing for the external componentry to be housed in a small unit capable of being worn behind the ear of the user. This unit allows the microphone, power unit and the speech processor to be housed in a single unit capable of being
30 discretely worn behind the ear, with the external transmitter coil still positioned on the side of the user's head to allow for the transmission of the coded sound signal from the speech processor and power to the implanted stimulator unit.

The external transmitter coil has traditionally been held in place via a
35 magnet which aligns with a magnet positioned within the internal receiver coil through magnetic attraction. Such a secure alignment ensures that both coils

are coupled efficiently so that the transfer of data and power is effectively performed. Whilst aiding in proper coil alignment, such a connection also provides a firm and secure method of holding the external coil in position on the head of the user, with the strength of this securing force being adjustable
5 through the use of variable strength magnets in the external coil. This method of securing the external and internal coils in close alignment is important for children and the like who are active and mobile and as such require a simple, yet effective means of ensuring that alignment of the coils is maintained. Early devices attempted to facilitate alignment of the internal and external coils
10 through a headband arrangement that was fitted around the head of the user to hold the coil in place. Such an arrangement proved troublesome as it could easily be knocked or unintentionally adjusted, especially with small children, and as such communication could easily be lost or reduced between the external device and the implant. Such an arrangement was also not
15 aesthetically pleasing.

A downside of the present system is the fact that for some people, the external coil is quite visible and cannot be easily hidden and as such they are conscious of this and the fact that their device is noticeable to others.
20 Therefore it is highly desirable to provide a system wherein the external components are relatively comfortable and easily worn so that the user does not feel self-conscious wearing the device.

Another issue with prior art devices is the fact that the magnet used to
25 facilitate and maintain proper alignment of the coils, prevents, or is detrimental to the effective use of magnetic resonance imaging (MRI) techniques, in the head region surrounding the implanted magnet. The presence of the magnet in such instances can distort the image taken from such a technique and in some instances the technique may even cause the implanted magnet to move,
30 causing problems with the implanted device. Therefore it would be highly desirable to provide an implant that allows recipients to utilise such a valuable medical diagnostic tool as an MRI, and ensure that such a technique can be undertaken without the risk of damage to the patient and/or device.

35 In order to overcome these disadvantages magnetless cochlear implants have been proposed, such as that disclosed in US Patent Number 6,141,591.

This patent discloses an implant that is strategically positioned via a set of alignment tools so that it can be aligned to communicate with an external controller/transmitter without the need for a magnet. The method of implantation requires a set of specific steps to ensure that the device is
5 embedded into the skull at the appropriate position, so that in use, the implant coil communicates with an external coil incorporated in an external unit worn behind the ear of the recipient. One problem with this particular device and method is that it requires the implant to be implanted by a relatively highly skilled surgeon to ensure the implant is positioned in the correct place. Still
10 further, should there be a change in the head shape, such as that which occurs during a child's growth, the implant may be placed such that the alignment with the external unit is not possible or ideal.

The present invention provides a cochlear implant system that is adapted
15 to address the above deficiencies of the prior art.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an
20 admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed in Australia before the priority date of each claim of this application.

Summary of the Invention

25

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements,
30 integers or steps.

There are instances when a conventional magnetic alignment system is desirable such as for a child, or in an active person, and as such there is a need to provide such individuals with a device that can be altered as the
35 individuals needs change. In the case of a young child, it has been found that a behind-the-ear (BTE) device is not an ideal solution as the ear may not be

sufficiently large enough to support a unit comfortable and securely. In such instances a magnet coil is far more beneficial to transmit data and energy to the implant, however as the child develops and grows to an age where system invisibility is important, there is a need to provide such a recipient with the
5 option for a less visible device.

Further to this, the choice of whether a magnetic alignment system is used or whether a less visible system is employed, remains the choice of the recipient. In this regard, it is important that the recipient has access to all such
10 options, with the options not being limited by the design of the particular implant. Traditional commercially available implants have been designed such that they can only be implanted in a particular orientation, with that orientation being dictated by the location of the exit point of the electrode array with respect to the implant package. There is a need to provide a device that can
15 be implanted in a number of orientations dependant upon the choice of the recipient.

The present invention offers the ability to provide a cochlear implant system that can operate in a conventional manner that utilises a magnet
20 connection to maintain the coils in alignment, and with a relatively minor procedure allows the device to be utilised in a magnetless manner. More specifically the present invention provides a reversible cochlear implant system that is designed in such a way as to allow the implant to be reversed in orientation so that instead of alignment with the coils occurring through a
25 magnet connection, the implanted coil can directly communicate with a unit worn behind the ear of the recipient without the need for use of magnets.

The present invention also offers the ability to provide a cochlear implant system that can operate in a conventional manner utilising a magnet
30 connection to maintain the coils in alignment, or can operate in a magnetless manner where the implanted coil can directly communicate with a unit worn behind the ear of the recipient without the need for the use of magnets.

According to a first aspect, the present application is directed to a first
35 invention comprising an implantable component of a cochlear implant system, the implantable component comprising:

a housing for a stimulator means, the stimulator means being adapted to output one or more stimulation signals; and

an electrode assembly adapted to apply electrical stimulation in accordance with the output of the stimulator means;

5 wherein on implantation, the electrode assembly extends from the housing at least initially in a downward orientation, toward the mastoid cavity.

According to a further aspect, the application is directed to a second invention comprising an implantable component of a cochlear implant system,
10 the implantable component comprising:

a housing for a stimulator means, the stimulator means being adapted to output one or more stimulation signals; and

an electrode assembly adapted to apply electrical stimulation in accordance with the output of the stimulator means;

15 wherein the housing has a lateral axis and is rotatable about said axis despite implantation of said electrode assembly.

In this aspect, the housing is preferably rotatable about said axis without leading to an adjustment of the implantation position of the electrode assembly.

20 In a preferred embodiment of this second aspect, the electrode assembly, on implantation, extends from the housing at least initially in a downward orientation.

25 Hereinafter, the electrode assembly defined in the above aspects is referred to as the first electrode assembly.

In a preferred embodiment of both aspects, the housing has at least an upper side and a lower side, the first electrode assembly extending from a
30 lower side of the housing.

In a further embodiment, the first electrode assembly comprises a carrier member having a leading end that is insertable into a cochlea of an implantee and a trailing end distal the leading end. The elongate carrier member
35 preferably has a plurality of electrodes mounted thereon. In one embodiment, the electrodes are mounted in a longitudinal array. Each of the electrodes have

at least one wire, and preferably at least two, extending from each electrode back towards the trailing end of the carrier member.

5 The wires preferably extend back to the housing to at least a first feedthrough in the wall of the housing. In one embodiment, the feedthrough is positioned in a lower face of the housing. In one embodiment, the feedthrough provides hermetic and insulated electrical connection for each wire extending from the electrode assembly into the housing of the implantable component. Each feedthrough can be formed using the method described in US Patent
10 5046242, the contents of which are incorporated herein by reference.

In one embodiment, the carrier member can have 22 electrodes. In another embodiment, the carrier member can have 30 electrodes. The electrodes are preferably formed from a biocompatible electrically conducting
15 material, such as platinum.

The elongate carrier member is preferably formed from a resiliently flexible material. In one embodiment, the carrier member can be preformed from a plastics material with memory.
20

In a preferred embodiment, the orientation of the carrier member as it is firstly inserted through a cochleostomy into the cochlea is preferably substantially straight. More preferably, the implantable orientation is straight. Following completion of implantation, the carrier member preferably adopts a
25 spirally curved configuration that matches the spiral nature of the scala tympani of the human cochlea. The carrier member is preferably pre-formed with this spiral configuration and is then straightened either during manufacture and packaging of the device or prior to implantation.

30 In a preferred embodiment, the elongate carrier member is formed from a suitable biocompatible material. In one embodiment, the biocompatible material can be a silicone, such as a flexible silicone elastomer-Silastic. Silastic MDX 4-4210 is an example of one suitable silicone for use in the formation of the elongate member. In another embodiment, the elongate
35 carrier member can be formed from a polyurethane or similar material.

In a preferred embodiment, the implantable component comprises a second electrode assembly. While it can be envisaged that the second electrode assembly could also be insertable in the cochlea, it is preferred that the second electrode assembly has one or more electrodes thereon and is adapted to be implantable external of the internal passages, such as the scala tympani, of the cochlea.

The second electrode assembly preferably extends from the housing, once implanted, at least initially in an upward orientation. In a further embodiment, the second electrode assembly preferably extends from an upper side of the housing. This second electrode assembly is typically implanted external of the cochlea in the muscle surrounding the head of the user. In this instance, the electrode assembly is referred to as an extra-cochlear electrode assembly and this allows the stimulation method known as monopolar stimulation to be performed. In monopolar stimulation the stimulation passes between an intracochlear and an extracochlear electrode, allowing for a wide current spread not normally achieved through interaction between intracochlear electrodes only.

The second electrode assembly preferably has one or more features defined herein in relation to the first preferably intracochlear electrode assembly. In a preferred embodiment, the second electrode assembly has one or two electrodes thereon.

In a further embodiment, the housing is preferably implantable in a recess of the temporal bone adjacent the ear of the implantee that is receiving the output of the implant system. The housing is preferably formed from a biocompatible material or has a biocompatible coating. The housing can be coated with a layer of silicone or parylene.

The implantable component preferably also comprises a receiver coil. The receiver coil preferably comprises a wire antenna coil. The antenna coil can be comprised of at least one, and preferably at least three, turns of electrically insulated platinum or gold wire tuned to parallel resonance by a capacitor internal to the housing. The electrical insulation of the antenna coil

can be provided by a flexible silicone moulding and/or silicone or polyurethane tubing.

5 The antenna coil is preferably external of the housing and is very thin enabling the coil, if desired, to be implanted behind the ear. Electrical connection between the antenna coil and componentry of the implantable componentry within the housing can be provided by two hermetic and electrically insulated ceramic feedthroughs or an electrical conductor. The ceramic feedthroughs can be formed using the method described in
10 abovementioned US Patent 5046242.

The receiver coil preferably has a maximum thickness that is less than the maximum thickness of the housing. In one embodiment, the antenna coil preferably has a thickness of about 2.5mm whereas the housing preferably has
15 a maximum thickness of about 3.5mm. The antenna coil preferably has a diameter of about 25mm.

The antenna coil of the implantable component preferably acts as part of a radio frequency (RF) link to allow transcutaneous bidirectional data transfer
20 between the implantable component and external components of the system. The link preferably further comprises an external antenna coil that is able to be aligned with the position of the implantable receiver coil. The radio frequency signals can be modified to encode data using the method described in US Patent 5741314. While described as a receiver coil, the receiver coil can
25 preferably transmit signals to the transmitter coil which receives the signals for the purpose of telemetry from the implanted receiver/stimulator unit.

The link between the two coils also provides a means of powering the componentry of the internal component. In the case where the implantable
30 component further has an on-board or implantable power source, such as a rechargeable battery, the link can provide a means of inductively charging the battery when required.

When implanted, the housing preferably contains, in addition to the
35 stimulator means, a receiver means. The receiver means is preferably adapted to receive signals from a controller means. The controller means is, in use,

preferably mounted external to the body of the implantee such that the signals are transmitted transcutaneously through the skin of the implantee.

5 The external controller can have a housing for a speech processor adapted to receive signals output by a microphone. During use, the microphone can be mounted in the housing that is preferably supported on the pinna of the implantee. Other suitable locations for the microphone and/or the housing can be envisaged, such as a lapel of the implantee's clothing.

10 The speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence is transferred to the implanted stimulator/receiver means using the transmitter and receiver coils. The implanted stimulator/receiver means
15 demodulates the modulated FM signal and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

The external controller preferably further comprises a power supply. The
20 power supply can comprise one or more rechargeable batteries. The transmitter and receiver coils are used to provide power via transcutaneous induction to the implanted stimulator/receiver means and the electrode array.

While the implant system can rely on external componentry, in another
25 embodiment, the controller means, including the microphone, speech processor and power supply can also be implantable. In this embodiment, the controller means can be contained within a hermetically sealed housing or the housing used for the stimulator means.

30 In a further embodiment, the antenna coil can be disposed about a magnet. The magnet, when present, is preferably centrally disposed in the receiver coil.

When present, the magnet can be used to hold and align an external coil
35 mounted to the outside of the head of the implantee. To achieve, this a magnetic material or another magnet arranged to experience an attraction force

to the magnet within the receiver coil can be positioned in a central location within the external coil.

In one embodiment, the magnet can be removable from its location
5 within the coil.

In a preferred embodiment, the receiver coil can be bent or deformed relative to the housing. Still further, the casing can preferably rotate about a lateral axis despite the first and/or second electrode assemblies being
10 connected thereto and in an implanted position within the implantee. In this regard, a surgeon, if desired, can rotate the housing about said lateral axis when a change in location of the receiver antenna coil is required within the head of the implantee. By rotating the housing about a lateral axis, the lower side of the housing preferably remains the lower side once the housing has
15 been rotated.

To facilitate the adjustment in orientation of the housing about the lateral axis, the housing can be fabricated from a resiliently flexible material that facilitates the change in orientation. For example, a region adjacent one or
20 both ends or one or both of the upper and lower sides can be deformed, bent or at least partially rolled up to facilitate the change in orientation of the housing in a surgical environment and despite the first and/or second electrode assemblies remaining in their originally implanted positions.

25 In yet a further embodiment, the change in orientation of the housing can result in the receiver coil moving from an implanted position that is aligned with or at least close to the position of the outer ear to a more distal location or vice versa.

30 This property of being rotatable about a lateral axis provides a cochlear implant system that can adjust to growth in dimensions of the implantee's head as can be expected as a baby grows into childhood and then further into adulthood.

35 For example, for a baby or young child, there are a number of advantages in utilising the magnetic alignment system. In particular, the

magnet serves to hold the external coil in the appropriate alignment with the internal coil which is important as such an implantee is unlikely to notice when the external coil has been dislodged or be physically unable to appropriately reposition the external coil on noticing dislodgment. As such, the magnetic alignment system serves to preferably prevent any such dislodgment. To use a magnetic alignment system, it is preferred that the external coil be positioned at least some distance from the external componentry. To accommodate this known requirement, the implantable component of the present invention would be firstly preferably implanted such that the implanted coil is at said distal location relative to the outer ear of the implantee that is likely to be supporting the external componentry.

As the child grows, the option is available with this implantable component for the implantee to undergo a further surgery in which the housing of the component is rotated about its lateral axis so bringing the receiver coil to a position more adjacent the outer ear of the implantee. During such a surgery, any magnet present in the receiver coil is preferably removed. In this case, alignment of the respective coils is provided by simply having the receiver coil in alignment with the position of the external coil supported on the external component. In this case, the external transmitter coil is preferably tucked behind the pinna of the outer ear and so is far less noticeable to other persons. Indeed, for a person with long and/or thick hair that extends over the ears, the presence of the external component may not be noticeable to casual inspection.

In a third aspect, the present invention is directed to a third invention comprising a method of adjusting the implanted position of a housing of an implantable component, the method comprising the steps of:

- accessing the site of implantation;
- rotating the housing about a lateral axis; and
- closing the implantation site.

In this aspect, the housing preferably has the features of the housing as defined herein in relation to the first and second aspects.

On initial implantation, the implantable component is preferably removably implanted within a recess in the mastoid bone of the implantee. The

component is preferably held in place using one or more fastening means that hold the component to the mastoid bone. In one embodiment, the fastening means can comprise one or more sutures extending from tie down members on the housing to the bone. In another embodiment, the fastening means can
 5 comprise bone screws that pass through receiving members of the housing and into the mastoid bone. Whatever fastening means is employed, the fastening means is preferably removable to allow the component to be rotated as described herein when desired.

10 Brief Description of the Drawings

By way of example only, a preferred embodiment of the invention is now described with reference to the accompanying drawings, in which:

15 Fig. 1 is a pictorial representation of a one example of a prior art cochlear implant system;

Figs. 2a and 2b are plan and side elevation views, respectively, of a prior art implantable component of a cochlear implant system;

20

Figs. 3a and 3b are plan and side elevation views, respectively, of one embodiment of an implantable component of a cochlear implant system according to the present invention;

25 Fig. 4 is an underneath plan view of a portion of the implantable component of Figs. 3a and 3b;

Fig. 5a is a side view of a behind-the-ear type external component of a cochlear implant for use with an implantable component implanted in a first
 30 orientation;

Fig. 5b is a side view of the external component of Fig. 5a but with the implantable component in a second different orientation relative to the external component;

35

Fig. 6 is a side view of one embodiment of an external component of Fig. 5a and Fig 5b showing one possible position of the external transmitter coil;

Fig. 7 is a side view of another embodiment of a external component;
5 and

Fig. 8 is a side elevational view of another embodiment of an external component.

10 Preferred Mode of Carrying out the Invention

A simplified conventional cochlear implant is shown in Figure 1. Cochlear implants typically consist of two main components, an external component including a speech processor 29, and an internal component
15 including an implanted receiver and stimulator unit 22. The external component includes an on-board microphone 27. The speech processor 29 is, in this illustration, constructed and arranged so that it can fit behind the outer ear 11. Alternative versions may be worn on the body. Attached to the speech processor 29 is a transmitter coil 24 which transmits electrical signals to the
20 implanted unit 22 via a radio frequency (RF) link.

The implanted component includes a receiver coil 23 for receiving power and data from the transmitter coil 24. A cable 21 extends from the implanted receiver and stimulator unit 22 to the cochlea 12 and terminates in an electrode
25 array 20. The signals thus received are applied by the array 20 to the basilar membrane 8 thereby stimulating the auditory nerve 9. The operation of such a device is described, for example, in US Patent No. 4,532,930.

The sound processor 29 of the cochlear implant can perform an audio
30 spectral analysis of the acoustic signals and outputs channel amplitude levels. The sound processor 29 can also sort the outputs in order of magnitude, or flag the spectral maxima as used in the SPEAK strategy developed by Cochlear Ltd.

35 Turning to Figure 2, there is shown a more detailed depiction of a typical implanted stimulator unit 22. This unit includes a receiver/stimulator package 3

which contains the associated implant electronics, capable of converting the received signals into stimulation patterns capable of delivery by the electrode array 20. A magnet 1 is positioned within the receiver coil 2 to assist in holding and aligning the external coil in place as previously discussed. As shown, the electrode array 20 exits from the receiver/stimulator package at one end of the device, typically the end remote from the receiver coil 2. The receiver stimulator package 3 is typically embedded and/or cemented within the mastoid bone in a hole drilled by the surgeon which both acts as a securing well to maintain the device in place, and also as a means to reduce the size of the device that extends beyond the bone of the patient. As can be understood, the configuration of such a device is designed such that it remains in the implanted orientation for the life of the patient, or at least until the device is removed. The orientation of the device cannot be substantially changed.

15 An implanted stimulator according to the present invention is depicted generally as 30 in Figs 3a and Fig. 3b. The stimulator 30 includes a receiver/stimulator package 31 and a receiver coil 32 attached thereto. A removable magnet 33 is positioned within the receiver coil 32 in much the same way as a conventional implant. In the present invention, however, the electrode array exits the stimulator substantially at right angles to the longitudinal axis of the stimulator 30. In the embodiment shown in Figure 3 the intra-cochlear array 20 exits from a first lower side of the stimulator 30 while the extra-cochlear array 38 exit from a second upper side of the stimulator 30. For clarity, the extra and intra-cochlear electrode arrays are not shown in their entirety in Figs 3a and 3b, however it is understood that such electrodes are well known in the art and as such do not require further explanation in this application.

30 The orientation of the stimulator 30 as depicted in Fig. 3a is representative of the orientation of the stimulator 30 on implantation. In other words, the stimulator is preferably implanted such that the intra-cochlear electrode 20 exits on the lower first side of the implant, towards the mastoid cavity.

35 The stimulator unit 30 is also symmetric about its longitudinal axis and considerably thinner than known implants. This allows for a relatively more

straightforward implantation surgery with bone drilling minimised. As is shown, a number of tie down points 39 are provided at strategic points on the implant to stabilise and secure the implant, resulting in both the initial implant surgery and any subsequent revision surgery being simpler and requiring less bone drilling than conventional surgeries.

Further to this, due to the present implant having a larger flat surface area, compared to known solid ceramic case implants, the implant is easy to stabilise. The implant is therefore much more cosmetic, having a less prominent device requiring less bone drilling, and has increased robustness and reduced size and is therefore more suitable for implantation into very young children.

Further when the recipient desires to convert the implant from a magnet version to a magnetless version, such as when a child matures to a stage when a BTE device can be reliably worn, the revision surgery required is very simple.

Figure 4 shows in more detail the connection of the intra-cochlear electrodes, the extra-cochlear electrodes and the receiver coil to the receiver/stimulator package 30. The intra-cochlear electrode 20 in this embodiment has 22 electrodes which are connected to the implant circuitry contained within the stimulator receiver package 30 via two feedthrough devices 41 and 42. These feedthrough devices maintain hermeticity with the implant circuitry allowing direct connection with the wires connected to the electrode elements of the array and extending back to the implant circuitry. The coil and the extra-cochlear electrode leads are also connected via these feedthroughs 41,42.

As can be seen in Figure 5a, the present invention allows for an implanted stimulator/receiver unit 30 that can be implanted in a conventional manner to communicate with an external coil 24. Alignment of the external coil 24 to the internal coil is provided by a magnet 33 in the internal coil 32.

Following minor surgery the orientation of the stimulator/receiver unit 30 can be reversed so that it can be operated directly by a BTE device 29 without the need for a separate external coil unit.

Figure 5a is a diagrammatical representation of one orientation of the implant of the present invention. This Figure shows the implant as being shaded and represents a conventional implant, wherein a behind-the-ear unit
5 29 is connected to the implant 30 via a remote external coil 24 held in alignment by the magnet 33. The external coil 24 is connected to the BTE processor 29 via a cable 40, and data and power is transferred across this link to the implant 30 via the aligned respective external and implanted receiver
10 BTE device is not suitable and a one piece on-the-head coil linked to a small body worn processor is desirable.

When a child matures to a stage where a BTE device can be reliably worn and is looking for a more cosmetically pleasing device, the individual may
15 undergo mild revision surgery to remove the magnet 33 from the stimulator 30 and reverse the orientation of the stimulator 30, so that the coil 32 is positioned towards the pinna with the receiver/stimulator unit towards the back of the skull, as is shown in Figure 5b. In this configuration the implant can be operated
20 directly by a BTE processor 29 having an integral transmitter coil, without the need for a separate cable and magnet aligned external coil. The alignment of the implanted receiver coil and the coil integral with the BTE device occurs due to revised position of the coil.

By having the electrode array leads exiting from the lateral sides of the
25 implant rather than the end of the implant, the array can be "flipped over" about a lateral axis to reverse the orientation of the implant without dislodging or displacing the intra-cochlear electrodes. The leads themselves have a degree of flexibility which allow them to be stretched/extended without causing deformation. The receiver coil 32 will also have a degree of flexibility, which
30 will allow the coil, surrounded by silicone, to bend to assist in the action of reversing the implant orientation.

A BTE device capable of being worn with the implant of the present invention in the magnetless configuration, is shown in Figures 6 and 7. In
35 Figure 6 a conventional BTE device is shown having an ear hook which is capable of securing the device in place behind the ear of the user, as well as a

body which houses the power source and/or speech processor. A microphone can be placed on the ear hook as described with reference to Figure 1. A coil can be made integral with the body of the BTE device so that when in place the BTE device communicates with the internal coil of the implant via the integral external coil. In Figure 7 another embodiment is described, which utilises an ear hook element to maintain the BTE device in place, but which allows the position of the coil 24 to be adjusted to take into consideration variations in the position of the internal coil, to ensure that optimum alignment is provided. This adjustment means may be in the form of a slider which can be moved relative to the ear hook. Yet another embodiment of a possible BTE device is shown in Figure 8 which depicts a BTE device with a movable arm 42 attached to a coil 24. In this embodiment the arm 42 can be moved along the body of the BTE device as well as laterally from the BTE device to ensure that correct alignment with the implanted coil is obtained.

15

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

20

Dated this eighth day of March 2002

Cochlear Limited
Patent Attorneys for the Applicant:

F B RICE & CO

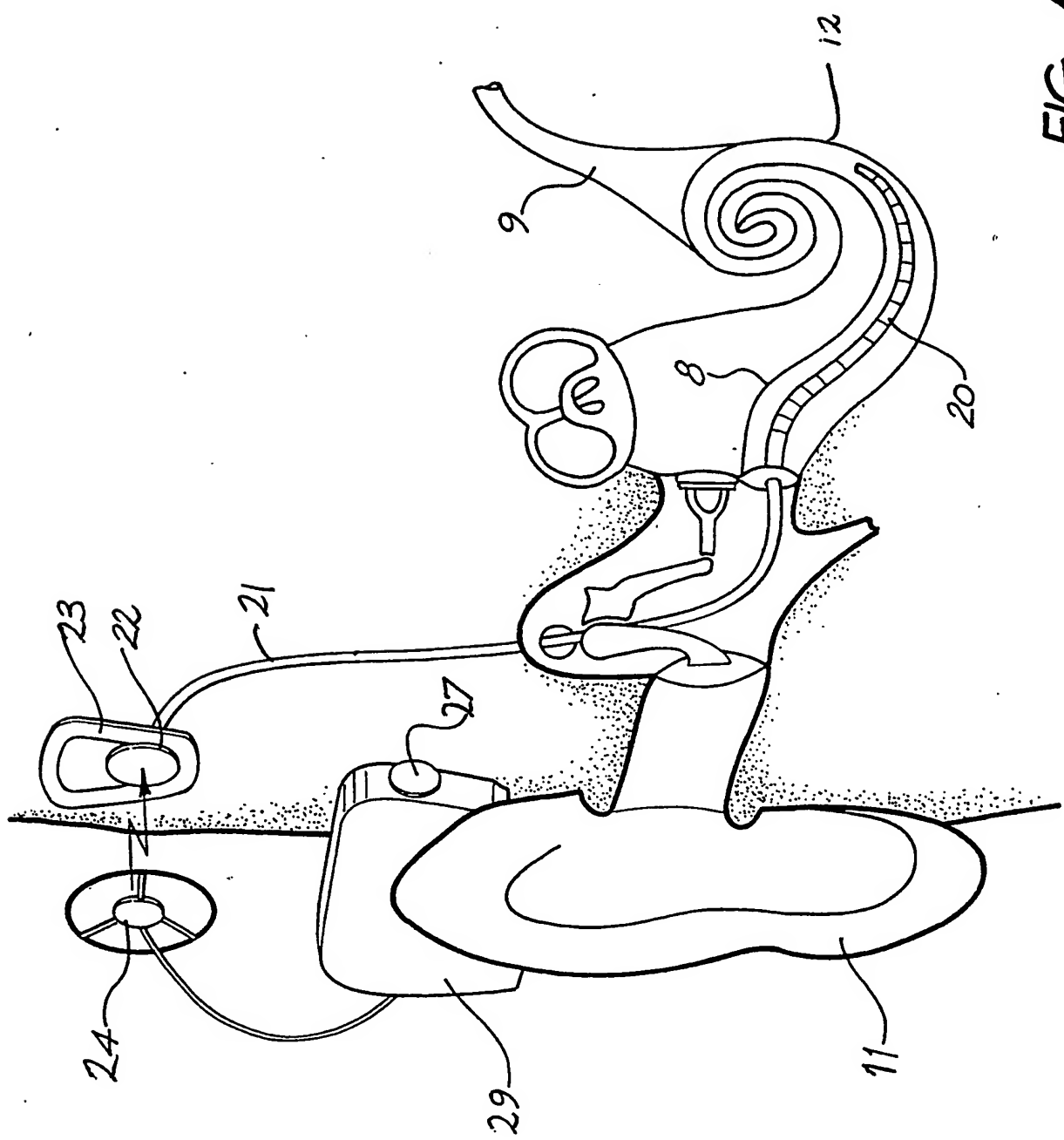


FIG. 1

Fig. 2b

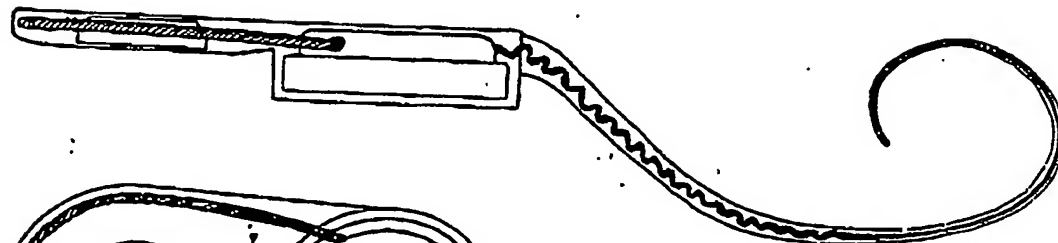
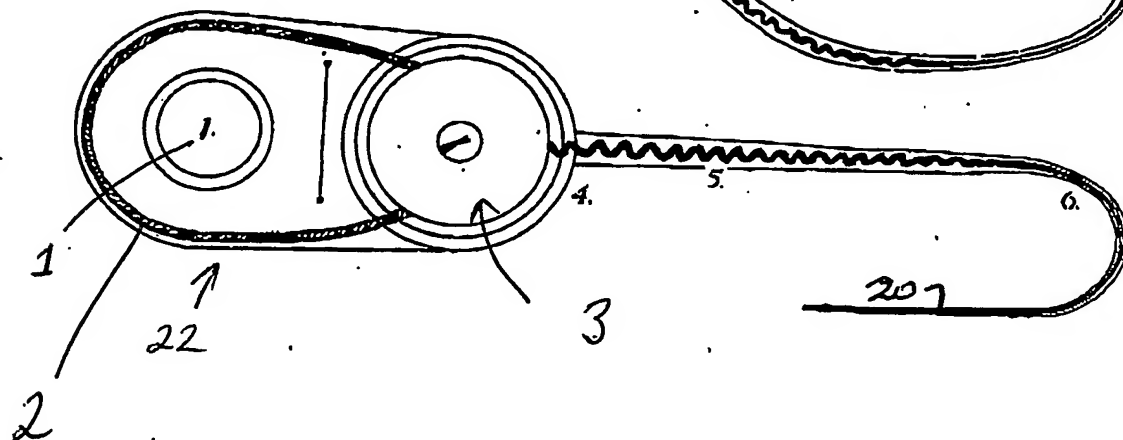
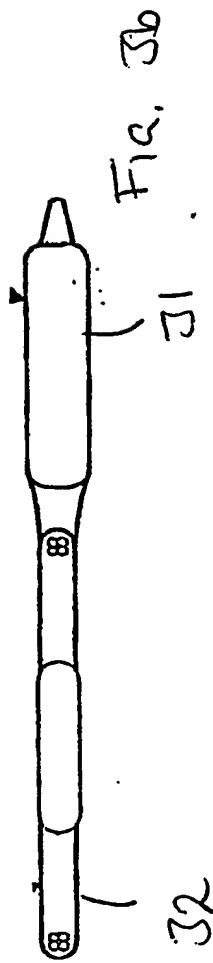
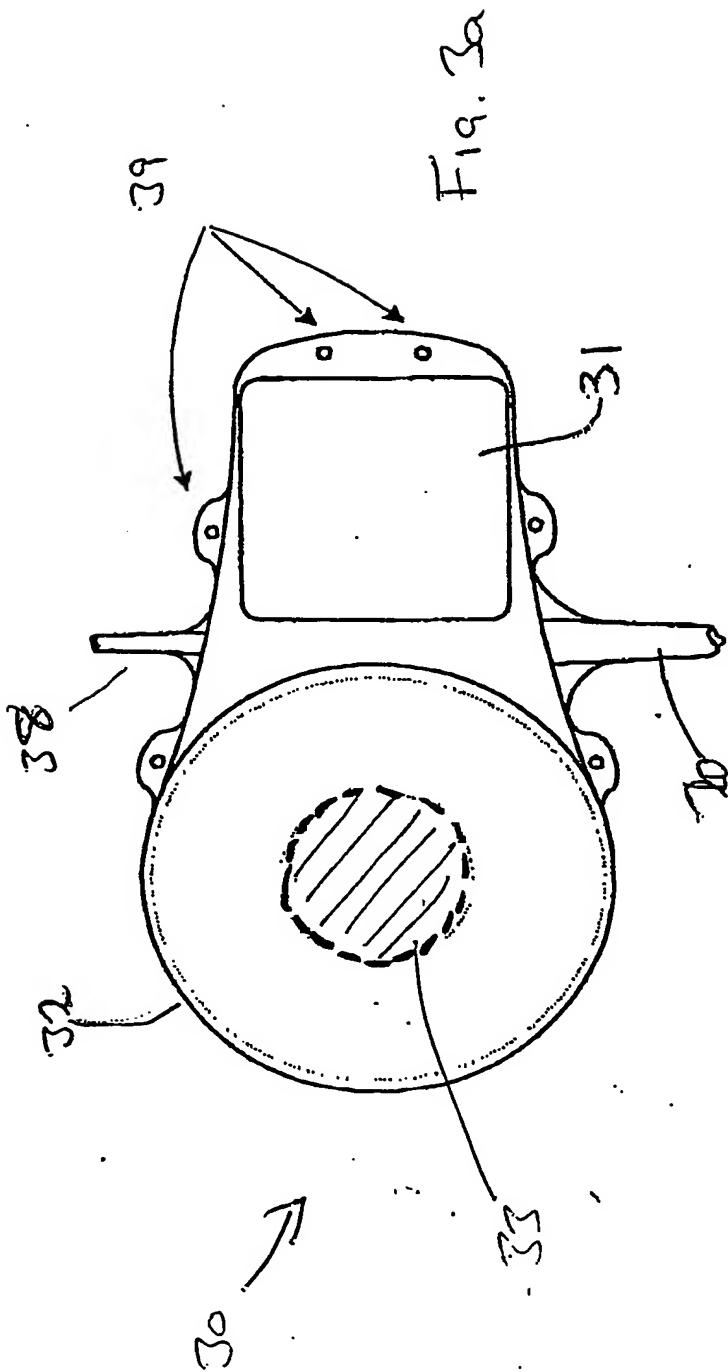


Fig. 2a



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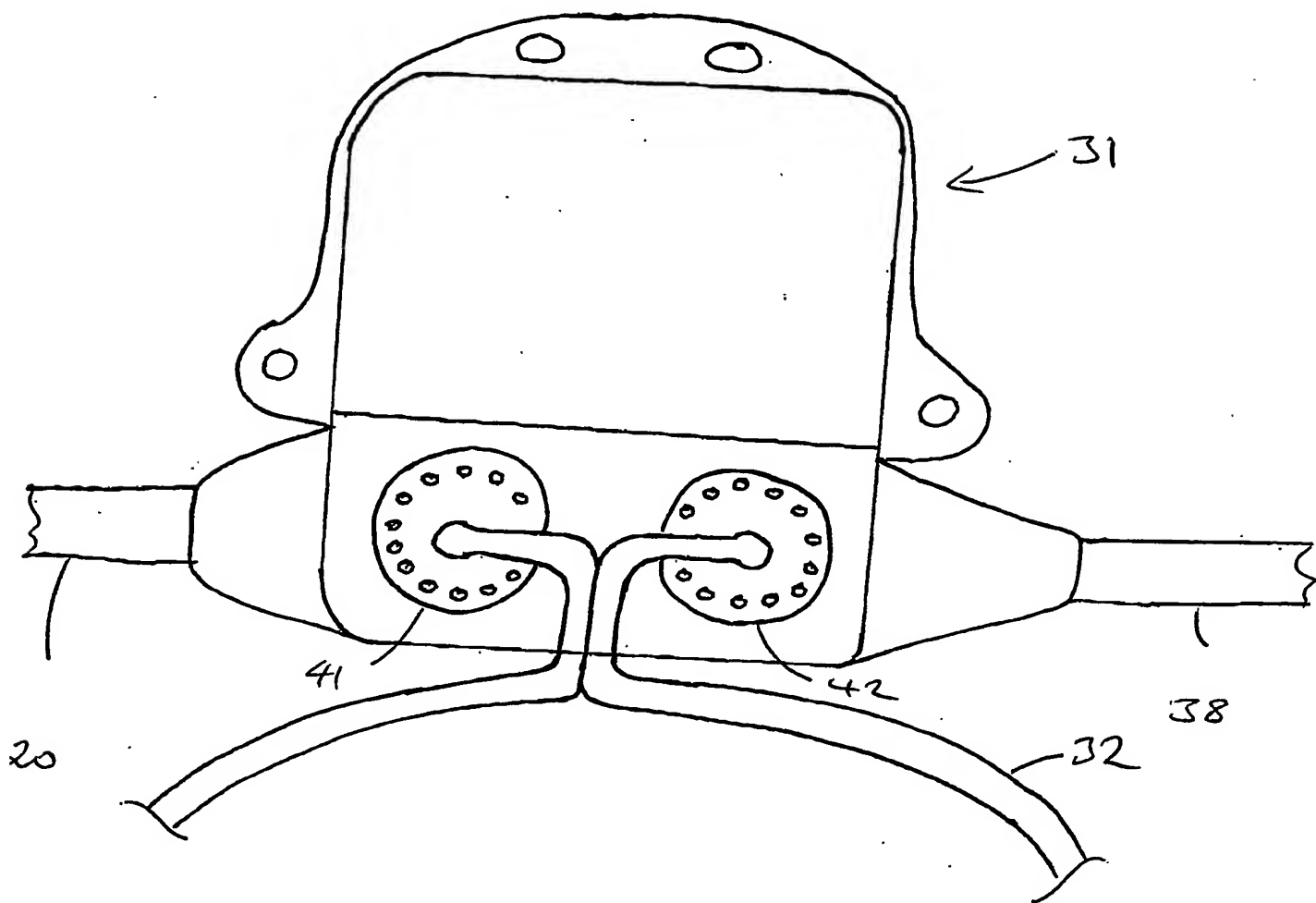


Figure 4

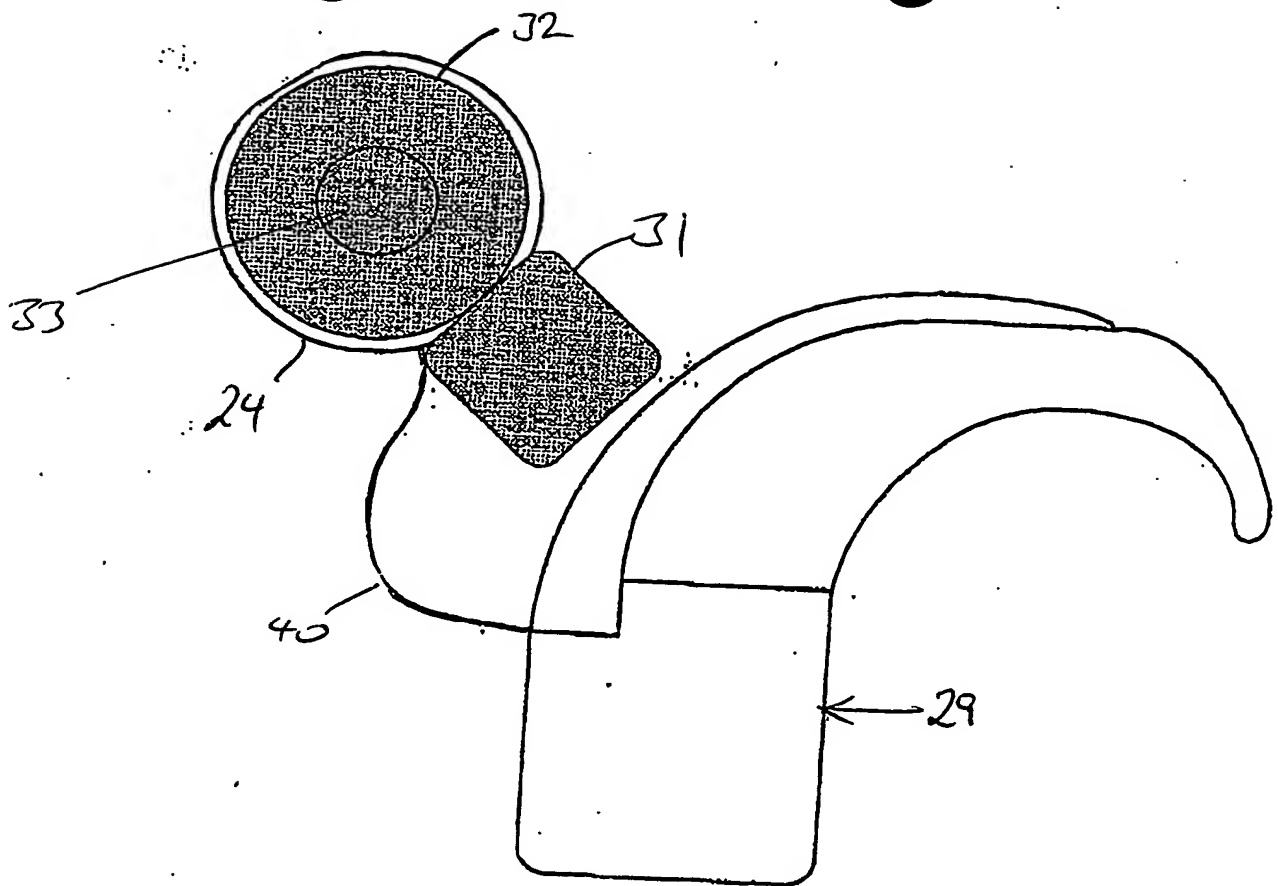


Figure 4a

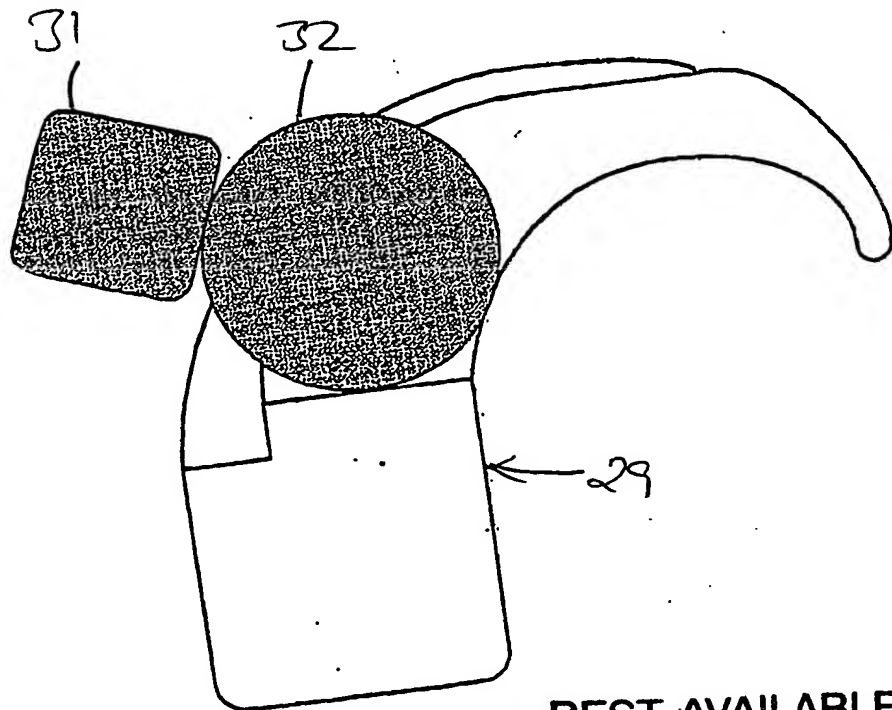


Figure 4b.

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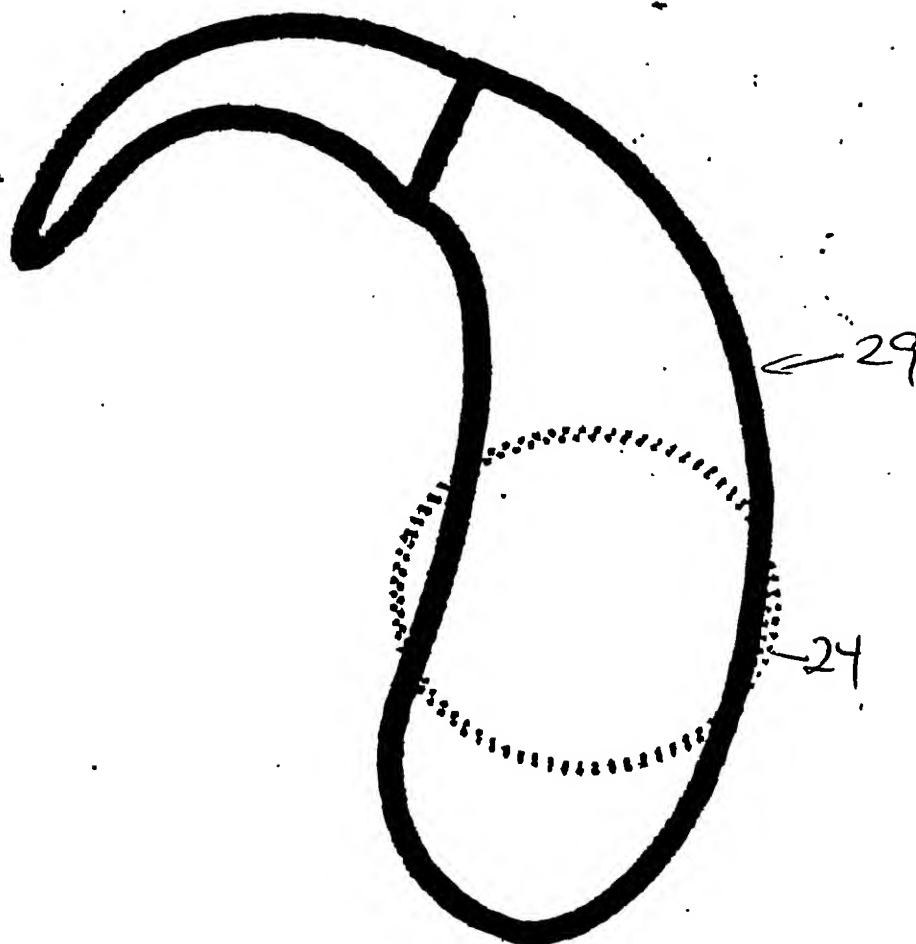


figure 5

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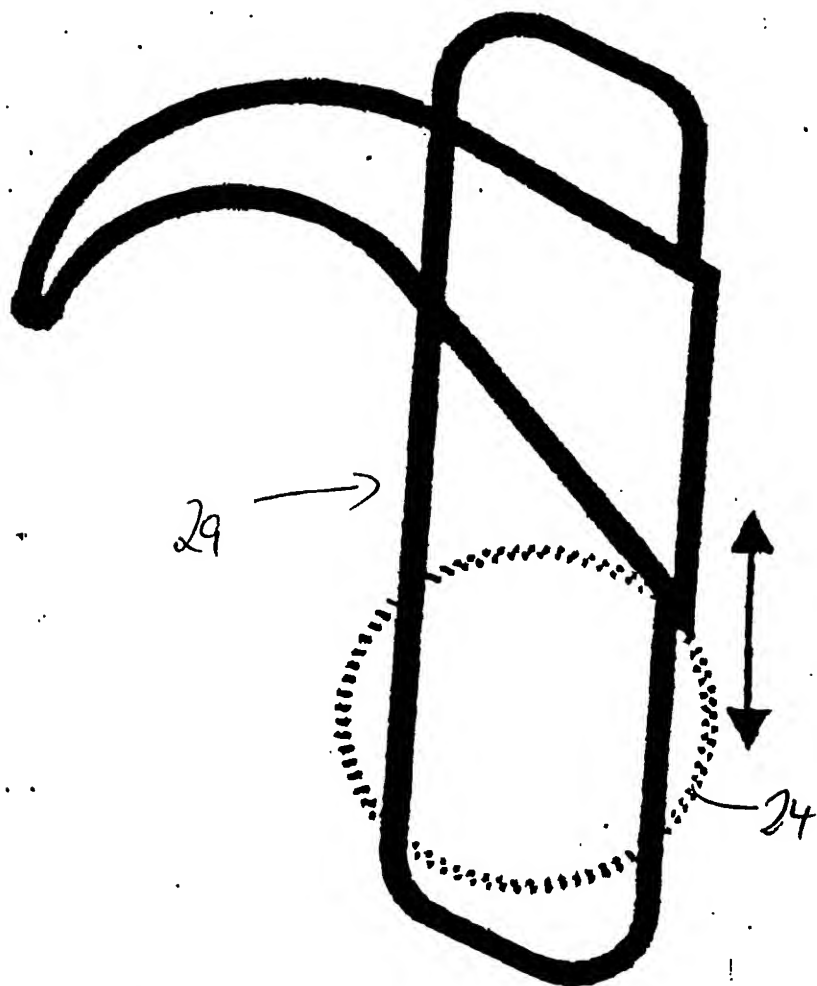


Figure 7

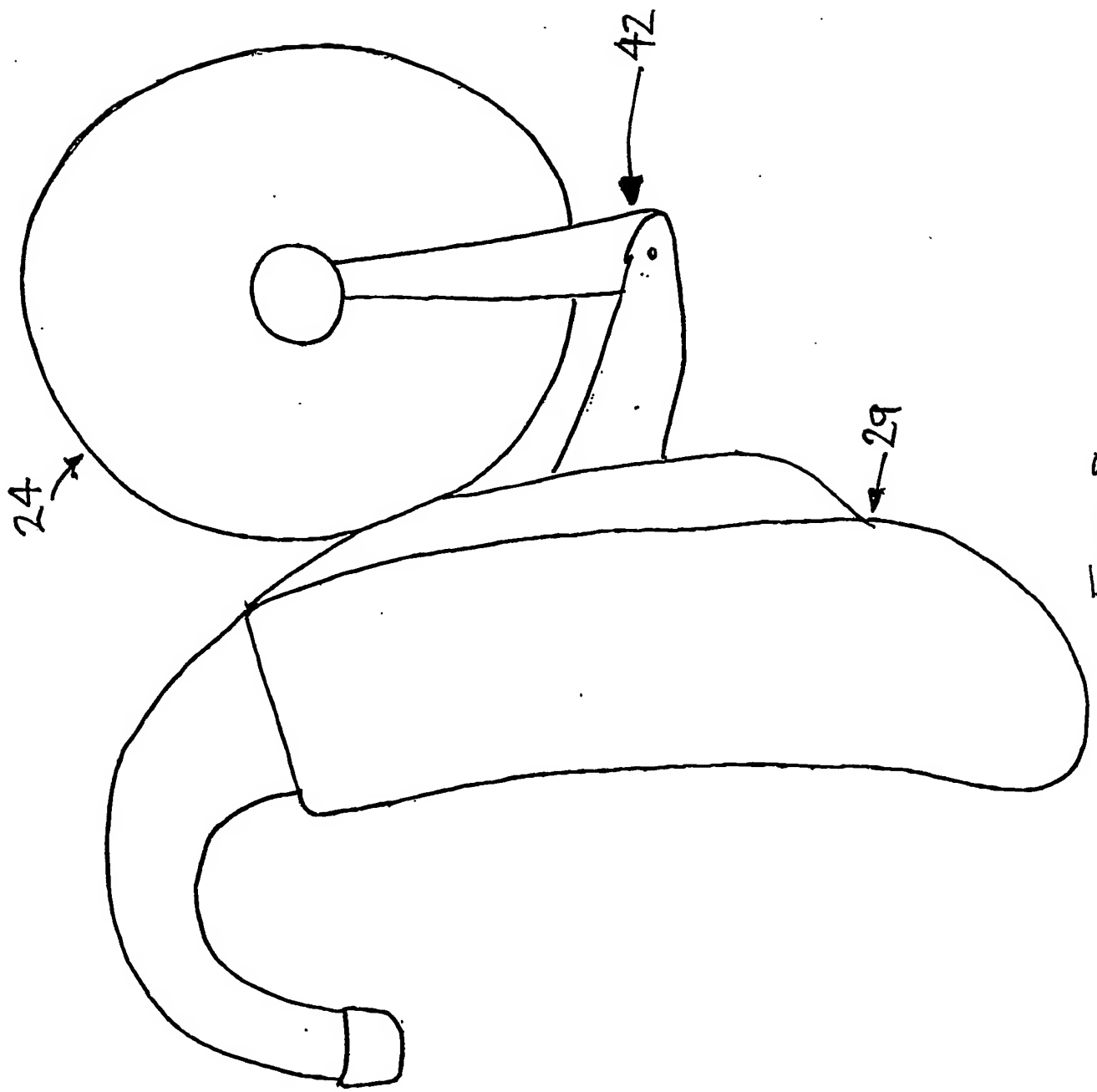


Figure 8